## 3.2.3 AFCEE Requirements for Development and Application of Uncertainty Analyses in Risk Assessment

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### Introduction

The risk characterization narrative is the most important part of the risk assessment because the risk managers rely on the narrative to make decisions. The uncertainty analysis is a critical element of the risk characterization; without the uncertainty analysis, the risk characterization would be little more than a collection of data, calculations, and estimates. The uncertainty analysis portion of the risk characterization—consisting of analysis, discussion, and conclusions—provides a balanced representation of the uncertainties associated with the earlier portions of the risk assessment and explains their relevance to the human health or environmental effects of concern. The discussion of uncertainty requires analysis and comment on such issues as (1) the quality and quantity of available data, (2) gaps in the database for specific chemicals, (3) the quality of the measurement data, (4) the use of default assumptions, and (5) the scientific judgments or science policy positions that were used to bridge information gaps. This discussion should lead to a statement of confidence in the risk assessment and the associated uncertainties.

### AFCEE Requirements

In both the human health and ecological risk assessments, the detail and sophistication required in the uncertainty analyses depend on whether the uncertainty evaluated is associated with a screening or baseline risk assessment. Although the uncertainty associated with a screening risk assessment will be substantially greater than that of a baseline assessment, the sources and degree of uncertainty associated with screening risk estimates are to be an integral part of the risk characterization sections of the screening assessments.

For baseline risk assessments, the uncertainty associated with all general assumptions will be evaluated, and their likely effect on the calculated risk estimate will be presented and explained (see exhibit 6-21, U.S. EPA, 1989, for example). Furthermore, for all baseline risk assessments, the uncertainty associated with the values selected for all parameters will be presented in individual tables for each exposure scenario evaluated. The table for each exposure scenario will include (1) identification of the parameter, (2) the range of values (observed or reasonable, as appropriate), (3) the midpoint value, (4) the value(s) used in the risk assessment, (5) the rationale for selecting the value(s) used, (6) the uncertainty associated with the value(s), and (7) the likely impact on the risk estimate. The sources of all literature values presented in the table will be provided. The information in the uncertainty table will include the degree to which selected parameter values likely vary from conservative yet reasonable values for the specific conditions of the site being evaluated. The tables will also address the impact of the selected value(s) on the risk assessment—whether and to what degree the value selected would tend to overestimate or underestimate the risk.

Based on the information described above, the noteworthy uncertainties—those that could have greatest impact on the estimated risk—will be identified and interpreted to provide a clear understanding about the consequential aspects of the assessment, including the likelihood of the estimated risk actually being realized by the receptor or assessment endpoint. This information will be developed and presented prominently with the risk estimate in the risk characterization portion of the risk assessment (U.S. EPA, 1989; 1995; 1998; 2000).

**Recommended Practices and Guidance**

The Environmental Restoration Program generally uses qualitative rather than quantitative methods to evaluate the uncertainty associated with (1) the general assumptions that are made, (2) the values selected for individual parameters of the risk assessment, and (3) the risk estimates themselves. Qualitative methods include a technical discussion that evaluates whether the assessments are representative of actual site conditions. The application of quantitative methods—such as Monte Carlo techniques—to analyze uncertainty is certainly not discouraged. However, the purpose of the uncertainty analysis is to give the risk manager insight into the risk characterization. Therefore, it is important to interpret the results of quantitative uncertainty assessments of selected elements of the risk assessment for their impact on the overall risk estimate relative to other elements whose uncertainty is qualitatively evaluated.

The uncertainty of the individual elements of the hazard identification, toxicity assessment, and exposure assessment could be presented in the risk characterization section of the human health risk assessment and the uncertainty associated with the individual elements of problem formulation, site investigation and analysis of exposure and effects, and verification and acceptance of sampling design could be presented in the risk characterization section of the ecological risk assessment. However, this approach is not recommended because it can introduce into important risk characterization narratives of the human health and ecological risk assessments voluminous information that has minimal impact on the estimated risk or contributes little to the understanding of the uncertainty associated with the risk estimates. Therefore, the recommended approach is to comprehensively address the uncertainties associated with the individual elements of the human health and ecological risk assessment in their respective sections or in an uncertainty section that precedes the risk characterization section. The uncertainty analysis for each section of the risk assessment should identify those elements that—because of their inherent contribution to the calculated risk or because of their associated uncertainty—may have a substantial impact on the estimated risk or on the understanding of the uncertainty associated with the risk estimate.

The uncertainty analysis, a critical element of the risk characterization, must be developed to provide a clear understanding to the risk manager concerning the consequential aspects of the risk assessment. Therefore, based on the uncertainty analyses of the individual risk assessment sections, the noteworthy uncertainties—those that could have greatest impact on the estimated risk—will be further interpreted in the risk characterization section (U.S. EPA, 1989; 1995; 1998; 2000). While the conventional practice is to make conservative assumptions in the absence of data, such assumptions

must be reasonable and the assessment results must be interpreted with caution. Information should be presented in the final assessment indicating that using reasonably conservative assumptions at multiple steps of the risk assessment may produce risk estimates that are overly conservative and thus unreasonable.

**References**

U.S. EPA. 1989. *Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual, Part A Baseline Risk Assessment, Interim Final (RAGS, Part A).* U.S. Environmental Protection Agency: EPA/540/1-89/002.

U.S. EPA. 1995. *Policy for Risk Characterization at the U.S. Environmental Protection Agency.* Issued by the Administrator of the U.S. Environmental Protection Agency (March).

U.S. EPA. 1998. *Guidelines for Ecological Risk Assessment, Final*. U.S. Environmental Protection Agency: EPA/630/R-95-002F.

U.S. EPA. 2000. "Risk Characterization," *Science Policy Council Handbook*. U.S. Environmental Protection Agency: EPA 100-B-00-002F.